REMARKS

Applicants thank the Office for the withdrawal of claim rejections under 35 USC 103(a) over Kouchiwa *et al.* (EP 0264259) in view of Chen *et al.* (US 6,544,556), over GB 747,293 in view of Chen *et al.*, and over Phillips I (US 5,840,737) in view of Phillips II (US 6,489,346).

Claims 1, 9 and 14 have been amended to include the limitation "wherein a ratio of the water-soluble acid neutralizer:water-insoluble acid neutralizer is about 1:20 to about 10:1." Support for the amendment can be found in the specification as filed, page 5, lines 26-page 6, line 7. The ratios are derived from the ranges for each neutralizer: water-soluble being present at 50 mg to 1,000 mg (page 6, lines 3-4) and water-insoluble being present at 100 mg to 1,000 mg (page 6, lines 5-6). Thus the ratio of water-soluble (50-1,000 mg): water-insoluble (100-1,000 mg) can be 50 mg:1,000 mg (1:20) to 1,000 mg:100 mg (10:1).

Claims 1, 3-17 and 19-21 are pending.

Rejection of claims under 35 USC 102(e)

The Office has rejected claims 1, 3-17 and 19-21 under 35 U.S.C. 102(e) as being anticipated by Phillips II (U.S. Pat. No. 6,489,346). Applicants respectfully traverse. Phillips II does not teach each and every limitation of the amended claims; in this case, the amended claims now recite the ratios of water-soluble and water-insoluble neutralizers.

In its rejection, the Office reasoned:

> Phillips II ('346) teaches a non-enteric coated solid pharmaceutical composition comprising a non-enteric coated proton pump inhibitor in a pharmaceutically acceptable carrier and at least one buffering agent and a method for treating acid-related gastrointestinal disorders comprising administering to a patient the non-enteric coated solid pharmaceutical composition. The pharmaceutically acceptable carrier comprises a bicarbonate salt of a Group IA metal and a carbonate salt of a Group IA metal (see Abstract; Claims); (col. 11, lines 36-44); (col. 13, line 47 -col. 14, line 26).
>
> Phillips II teaches that mixtures of the buffering agents can be utilized (column 13, lines 47-53). Suitable buffering agents disclosed include sodium bicarbonate, potassium bicarbonate, magnesium hydroxide, aluminum hydroxide, aluminum hydroxide/sodium bicarbonate co-precipitate, sodium carbonate and calcium carbonate (see col. 13, line 63 - col. 14, line 14); (col. 17, lines 58-60).
>
> The non-enteric proton pump inhibitors include a substituted benzimidazole of lansoprazole or an enantiomer, isomer, derivative, free base or salts thereof (see Abstract).
> The instant invention is anticipated by Phillips.

The amendments to claims 1, 9 and 14, from which the remaining rejected claims depend, obviate the rejection because Phillips II neither teaches nor suggests a ratio of the water-soluble acid neutralizer:water-insoluble acid neutralizer being about 1:20 to about 10:1. Phillips II, instead, only teaches percentages of a water soluble acid neutralizer, a Group IA metal bicarbonate salt, being present in the composition from about 5% to 60% (column 14, lines 18-26). Because Phillips II does not teach each and every limitation of the rejected claims, the rejection is no longer applicable. Applicants respectfully request the Office to withdraw the rejection.

Rejection of claims under 35 USC 103(a)

The Office has rejected claims 1, 3-17 and 19-21 under 35 U.S.C. 103(a) as being unpatentable over Phillips (U.S. Pat. No. 6,489,346). Applicants respectfully traverse, because Phillips II does not teach or suggest a ratio of the water-soluble acid neutralizer:water-insoluble acid neutralizer being about 1:20 to about 10:1.

The Office reasoned:

> Phillips ('346) teaches a non-enteric coated solid pharmaceutical composition comprising a non-enteric coated proton pump inhibitor in a pharmaceutically acceptable carrier and at least one buffering agent and a method for treating acid-related gastrointestinal disorders comprising administering to a patient the non-enteric coated solid pharmaceutical composition. The pharmaceutically acceptable carrier comprises a bicarbonate salt of a Group IA metal and a carbonate salt of a Group IA metal (see Abstract; Claims); (col. 11, lines 36-44); (col. 13, line 47 -col. 14, line 26).
>
> Phillips teaches that mixtures of the buffering agents can be utilized (column 13, lines 47-53). Suitable buffering agents disclosed include sodium bicarbonate, potassium bicarbonate, magnesium hydroxide, aluminum hydroxide, aluminum hydroxide/sodium bicarbonate co-precipitate, sodium carbonate and calcium carbonate (see col. 13, line 63 - col. 14, line 14); (col. 17, lines 58-60).
>
> The non-enteric proton pump inhibitors include a substituted benzimidazole of lansoprazole or an enantiomer, isomer, derivative, free base or salts thereof (see Abstract).
>
> The instant invention, when taken as a whole, would have been *prima facie* obvious given the teachings of Phillips. Phillips teach a non-enterically coated formulation that uses both water-soluble as well as water-insoluble acid neutralizers, that function to protect the PPI from acid degradation. Thus, the bioavailability of the proton pump inhibitor is preserved to provide for the effective treatment and/or prevention of gastric acid related disorders.

The amendments to claims 1, 9, and 14 obviate the rejection since Phillips II neither teaches nor suggests a ratio of the water-soluble acid neutralizer:water-insoluble acid neutralizer being about 1:20 to about 10:1. Phillips II, instead, only teaches percentages of a water soluble acid neutralizer, a Group IA metal bicarbonate salt, being present in the composition from about 5% to 60% (column 14, lines 18-26). Because Phillips II does not teach each and every limitation of the rejected claims, the rejection is no longer applicable. Applicants respectfully request the Office to withdraw the rejection.

REQUEST FOR RECONSIDERATION

Reconsideration and withdrawal of all claim rejections are respectfully requested. Applicants believe that the present application is in condition for allowance. Should the Examiner have any questions or would like to discuss any matters in connection with the present application, the Examiner is invited to contact the undersigned at (312) 627-2126.

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